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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,851	06/05/2000	HANS ACHENBACH	A32964PCT/U	6879

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EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/463,851	Applicant(s) Achenbach, H.
	Examiner Patricia Patten	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 12, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *53, 57, 59, 60, 63-70, and 72-80* is/are pending in the application.

4a) Of the above, claim(s) *74-80* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *53, 57, 59, 60, 63-70, 72, and 73* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 53, 57, 59-60, 63-70 and 72-80 are pending in the application.

Newly submitted claims 74-80 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 74-80 are drawn to a method for inhibiting mutagenesis in an organism with a specific compound derived from A.taliscana, and a method for treating a chronic inflammatory disease in a subject comprising administration of an organic solvent extract of A.taliscana. The method for inhibiting mutagenesis with the specific compounds as claimed is properly restrictable from a method for inhibiting mutagenesis with an extract of A.taliscana. Because the products are different, the effects would necessarily be different when administered to an organism. Subsequently, a method for treating an inflammatory disease is a patentably distinct method from inhibiting mutagenesis. The methods have different modes of operation, they have different functions, and they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. The search for each of the above inventions is not co-extensive *particularly with regard to the literature search*. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 74-80 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 53, 57, 59-60, 63-70 and 72-73 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

Declaration

The Declaration filed under 37 CFR 1.132 on 3/12/03 was entered into the file. However, because the Declaration is solely related to claims which have not been entered, the declaration will not be considered at this time.

Claim Rejections - 35 USC § 112

Claims 53, 57-60 and 63-64 remain rejected and new claims 72-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting plant fungal growth *in-vitro* or inhibiting mutagenesis in a microorganism via administration of an organic solvent extract of *Aristolochia taliscana*, does not reasonably provide enablement for a method for inhibiting mutagenesis or inhibiting fungal growth in any organism such as mammals.

Applicant's arguments were fully considered but not found persuasive.

Applicant provides several Exhibits which show that some agents which showed mutagenesis ability via use of the Ames test, proved inhibitory *toward certain tumor cells in vitro* or in *certain mammals* (i.e., mice or rats). These Exhibits were fully considered. However, this is not a clear evidence that the extract from *A.taliscana* will work commensurate in scope with the claimed invention. It is noted that the claims remain broad enough to cover any mutagenesis (i.e., cancer caused by DNA mutations) and any organism (i.e., humans). Although it is accepted that certain substances which have been shown to inhibit mutagenesis via Ames testing have actually shown some positive results in vitro, or in vivo with mice and rats, this does not provide a clear nexus between Ames testing and in vivo or even in vitro results

especially with regard to mutagenesis which is difficult and rare to treat such as cancer. Thus, the skilled artisan would not have an expectation that the composition as claimed would work commensurate in scope with the claimed invention.

Applicant has shown *one* mutagen which was inhibited with an extract of *A.taliscana* and contends that this is evidence that the extract will inhibit all mutagens acting on any organism. It is well known and widely accepted that each mutagenic substance will produce a distinct response in-vivo, hence the need for a multitude of diverse anti-mutagenic drugs. Applicant has not demonstrated, and it is not known in the art what other types of mutagens, out of a plethora of potential mutagens the composition of the Instant invention will actually inhibit. It is further noted that the mechanisms of the extract are not known. Inhibition of a mutagen in bacteria can be markedly different than inhibition of mutagenesis in a mammal.

The question is, how much experimentation would be involved for the skilled artisan to bridge the gap between where Applicant has left off, and the breadth of the claimed Invention? The Applicant has shown that an extract from A.taliscana has inhibited one mutagenesis agent in two bacteria according to the data in the Instant specification. However, the claims are drawn to a virtual plethora of possible mutations (including cancer) and any type of organism (including humans). Some mammalian cancers are manifested from mutagenic causing agents. However, Applicants have

not demonstrated the effectiveness of *A.taliscana* extract on inhibition of mutagen manifested cancers. The skilled artisan would not have a reasonable expectation that inhibition of one mutagen, which is mutagen specific, to inhibit all mutagens in all organisms such as humans. For example, the skilled artisan would not reasonably expect for the *A.taliscana* extract to inhibit thymine dimers in mammalian DNA caused from UV rays for example, because the mutagenic activity of UV is vastly different than the mutagenic properties of 2-amino-anthracene or 2-nitrofluorene.

Claim Rejections - 35 USC § 102

Claims 68-70 remain rejected under 35 U.S.C. 102(b) as being anticipated by de la Parra (US 4,782,077) for the reasons set forth in the Office Actions dated 1/4/01 and 9/10/02.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues that the limitations found in claims 68-70 are not found in de la Parra and are therefore not anticipated. However, claims 68-70 recite that they are organic solvent extracts of A.taliscana. Because the de la Parra disclosed an organic solvent extract of A.taliscana, the limitations found in the claims must have been an

inherent property of the extract produced by de la Parra absent sufficient evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over de la Parra (US 4,782,077). Claims 65-67 have been amended to recite wherein the extraction is carried out at room temperature.

The teachings of de la Parra were discussed in a previous Office action. De la Parra did not specifically teach wherein the extraction was carried out at room temperature.

Applicant's arguments were considered, but not found convincing.

Applicant contends that because the prior art process used a Soxhlet extractor which typically employs heat, that the composition disclosed by De la Parra would be patentably distinct from the Instantly claimed invention which performs the reaction at room temperature.

One of ordinary skill in the art would have had a reasonable expectation that carrying out the extraction at room temperature would have afforded a product that was substantially the same as an extract obtained from a Soxhlet extraction. It is well known in the art that heat drives a reaction to completion quicker than room temperature. Thus, although the Soxhlet apparatus was well known to be a more efficient tool in performing extraction, the ordinary artisan would have had a reasonable expectation that the organic solvent extraction would have afforded a similar product, if not the same product.

Thus, absent sufficient evidence to the contrary, the composition derived from the extraction of *A.taliscana* with an organic solvent would have been the same independent upon the temperature of the reaction.

Claims 53 and 55-64 remain free of the art.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220 The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER R. TATE
PRIMARY EXAMINER